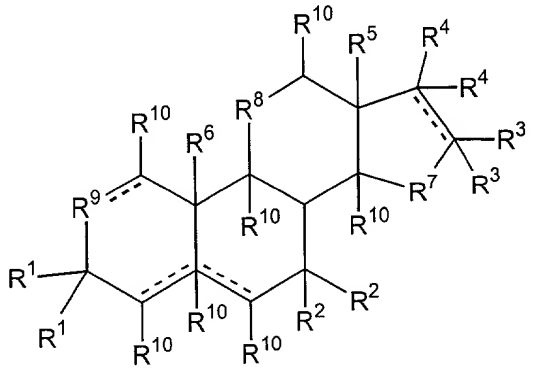
CLAIMS

What is claimed is:

1. A method to modulate an immune response or cellular response in a subject in need thereof comprising administering to the subject, or delivering to the subject's tissues, an effective amount of a compound of formula 1



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wherein,

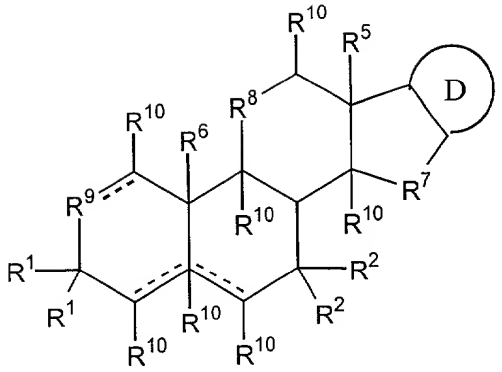
each R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} independently are -H, $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, -O-Si-$(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, $-NO_2$, $-OSO_3H$, $-OPO_3H$, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted heterocycle, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide, a polymer, or,

one or more of both R^1, R^2, R^3 or R^4 together comprise an independently selected spiro ring, or

one more of R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} are =O, =S, =N-OH, $=CH_2$, or a spiro ring and the hydrogen atom or the second variable group that is bonded to the same carbon atom is absent, or,

one or more of two adjacent R^1-R^6 and R^{10} comprise an independently selected ketal or thioketal, or

all R^3 and R^4 together comprise a structure of formula 2



2;

R^7 is $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-O-C(R^{10})_2-$, $-C(R^{10})_2-S-C(R^{10})_2-$, $-C(R^{10})_2-NR^{PR}-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$;

R^8 and R^9 independently are $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$, or one or both of R^8 or R^9 independently are absent, leaving a 5-membered ring;

R^{13} independently is C_{1-6} alkyl;

R^{PR} independently is -H or a protecting group;

D is a heterocycle or a 4-, 5-, 6- or 7-membered ring that comprises saturated carbon atoms, wherein 1, 2 or 3 ring carbon atoms of the 4-, 5-, 6- or 7-membered ring are optionally independently substituted with -O-, -S- or $-NR^{PR}-$ or where 1, 2 or 3 hydrogen atoms of the heterocycle or where 1, 2 or 3 hydrogen atoms of the 4-, 5-, 6- or 7-membered ring are substituted with $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-O-Si-(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, $-NO_2$, $-OSO_3H$, $-OPO_3H$, an ester, a thioester, a phosphoester, a phosphothioester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted hetercycle, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide or a polymer, or,

one more of the ring carbons are substituted with =O, =S, =N-OH, $=CH_2$, or a spiro ring, or

D comprises two 5- or 6-membered rings, wherein the rings are fused or are linked by 1 or 2 bonds, but provided the formula 1 compound is not 4-pregnene-11β,17α,21-triol-3,20-dione, 17α,21-dihydroxypregn-4-ene-3,11,20-trione, 11β,21-dihydroxy-3,20-dioxopregn-4-en-18-al, 11β,17α,21-trihydroxypregna-1,4-diene-3,20-dione, 17α,21-dihydroxypregna-1,4-diene-3,11, 20-trione, 3β-hydroxypregn-5-ene-20-one, 3β-hydroxyandrost-5-ene-17-one, pregn-4-ene-3,20-dione, 21-hydroxypregn-4-ene-3,20-dione, 9-fluoro-11β,16α,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione, 9-fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, 9-fluoro-11β,17α,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione or an ester or ether of any of these,

and provided that one or more of the following apply (1) the formula 1 compound is administered to the subject, or delivered to the subject's tissues using an intermittent dosing protocol,

or (2) the formula 1 compound is a component in a liquid formulation that comprises less than about 3% v/v of water and one or two of R^7, R^8 or R^9 independently are -O-, -S- or -NH-, or at least one of R^1-R^6 and R^{10} is an amino acid, or a double bond is present at the 1-2 position, 4-5 position or at the 16-17 position, or at least one of R^1-R^4 independently is a -SH, a halogen, or a carbamate,

or (3) the formula 1 compound is a component in a buccal or sublingual formulation that optionally comprises one or more of sucrose, mannitol, povidone and magnesium stearate;

or (4) one or two of R^7, R^8 or R^9 independently are -O-, -S- or -NH-,

or (5) at least one of R^1-R^6 and R^{10} is an amino acid,

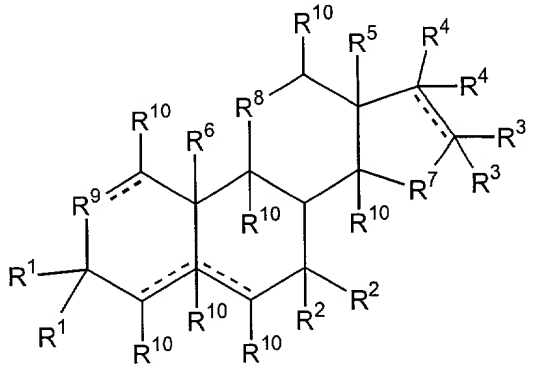
or (6) a double bond is present at the 1-2 position, 4-5 position or at the 16-17 position.

2. The method of claim 1 wherein the immune response or the cellular response is an enhanced Th1 immune response, a reduced Th2 immune response, reduced inflammation, enhanced hemopoiesis, inhibited tumor cell proliferation, inhibited replication of a pathogen or amelioration of a symptom of any of these conditions.

3. The method of claim 2 wherein the reduced inflammation is in a subject suffering from an autoimmune condition or an inflammation condition.

4. The method of claim 3 wherein the autoimmune condition or the inflammation condition is rheumatoid arthritis, osteoarthritis, systemic lupus erythematosis, asthma, multiple sclerosis, an infection or vascular inflammation.

5. A composition comprising a compound of formula 1



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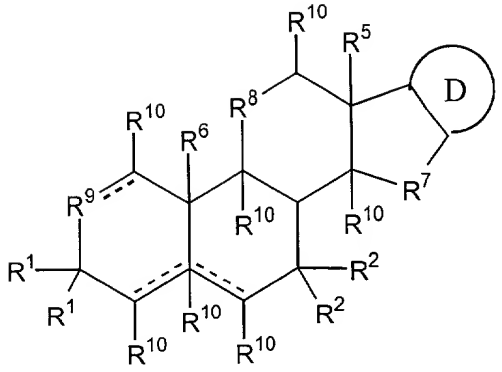
and one or more nonaqueous liquid excipients, wherein the composition comprises less than about 3% v/v water and wherein,

R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} independently are -H, -OR^{PR}, -SR^{PR}, -$N(R^{PR})_2$, -O-Si-$(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, -NO_2, -OSO_3H, -OPO_3H, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide, a polymer, or,

one, two or more of R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} independently are =O, =S, =N-OH, =CH_2 or a spiro ring and the hydrogen atom or second variable group that is bonded to the same carbon atom is absent, or,

one or more of two adjacent R^1-R^6 and R^{10} comprise an independently selected ketal or thioketal, or

R^3 and both R^4 together comprise a structure of formula 2



2;

R^7 is $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-O-C(R^{10})_2-$, $-C(R^{10})_2-S-C(R^{10})_2-$, $-C(R^{10})_2-NR^{PR}-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$;

R^8 and R^9 independently are $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$, or one or both of R^8 or R^9 independently are absent, leaving a 5-membered ring;

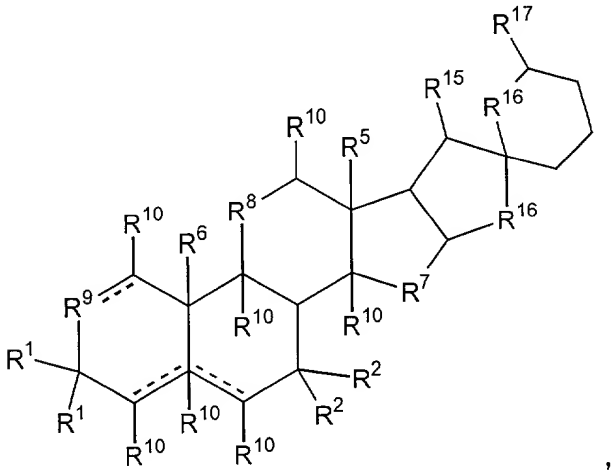
R^{13} independently is C_{1-6} alkyl;

D is a heterocycle or a 4-, 5-, 6- or 7-membered ring that comprises saturated carbon atoms, wherein 1, 2 or 3 ring carbon atoms of the 4-, 5-, 6- or 7-membered ring are optionally independently substituted with -O-, -S- or $-NR^{PR}-$ or where 1, 2 or 3 hydrogen atoms of the heterocycle or where 1, 2 or 3 hydrogen atoms of the 4-, 5-, 6- or 7-membered ring are substituted with $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-O-Si-(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, $-NO_2$, $-OSO_3H$, $-OPO_3H$, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide or a polymer, or,

one or more of the ring carbons are substituted with =O, =S, =N-OH, $=CH_2$ or a spiro ring and the hydrogen atom that is bonded to the same carbon atom is absent, or

or D comprises two 5- or 6-membered rings, wherein the rings are fused or are linked by 1 or 2 bonds, but provided the formula 1 compound is not 4-pregnene-11β,17α,21-triol-3,20-dione, 17α,21-dihydroxypregn-4-ene-3,11,20-trione, 11β,21-dihydroxy-3,20-dioxopregn-4-en-18-al, 11β,17α,21-trihydroxypregna-1,4-diene-3,20-dione, 17α,21-dihydroxypregna-1,4-diene-3,11, 20-trione, 3β-hydroxypregn-5-ene-20-one, 3β-hydroxyandrost-5-ene-17-one, pregn-4-ene-3,20-dione, 21-hydroxypregn-4-ene-3,20-dione, 9-fluoro-11β,16α,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione, 9-fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, 9-fluoro-11β,17α,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione or an ester or ether of any of these.

6. The composition of claim 5 wherein formula 2 has the structure



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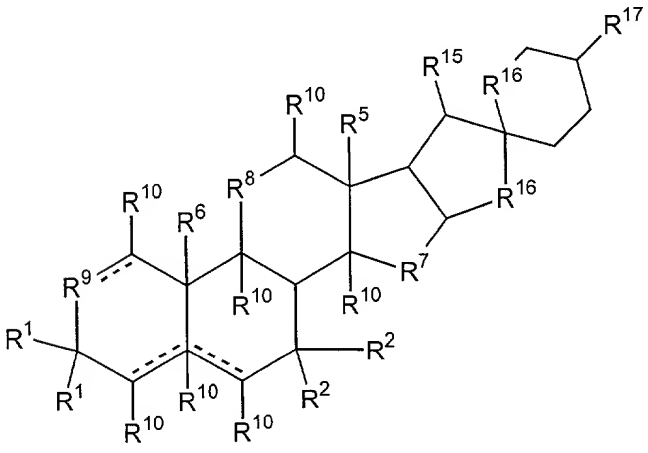

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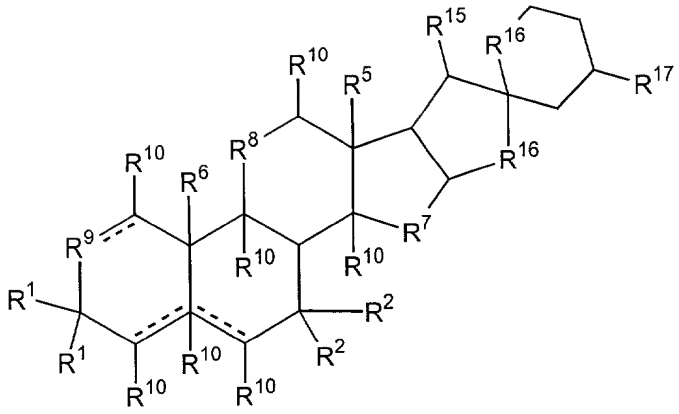

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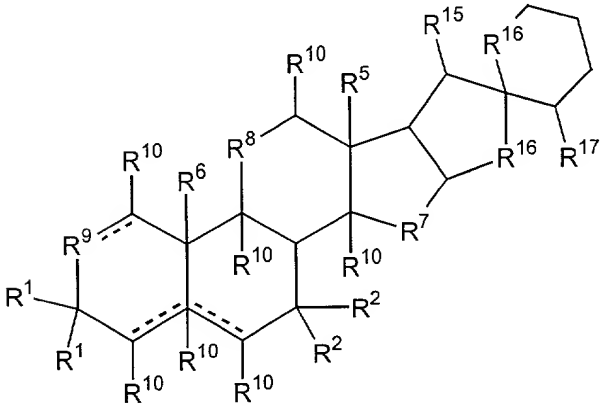

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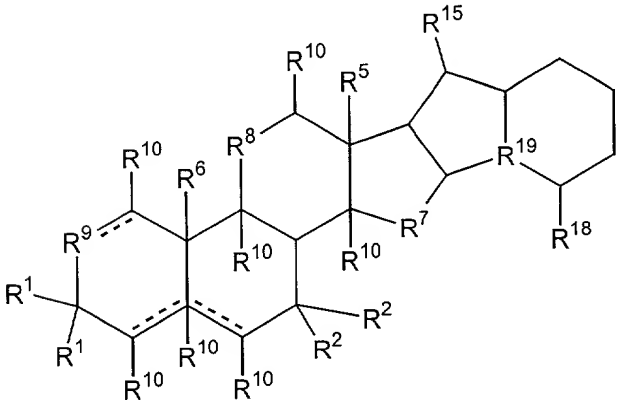

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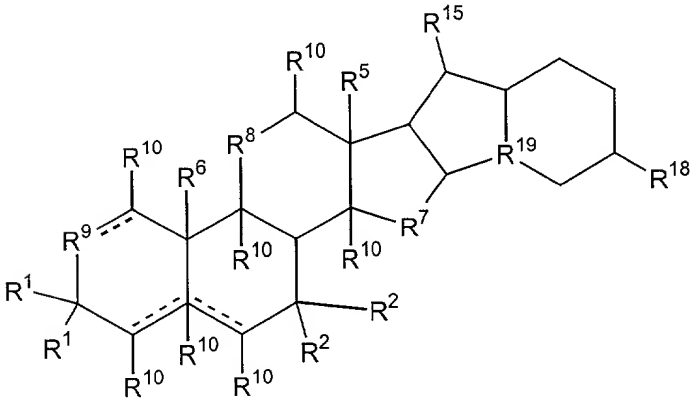

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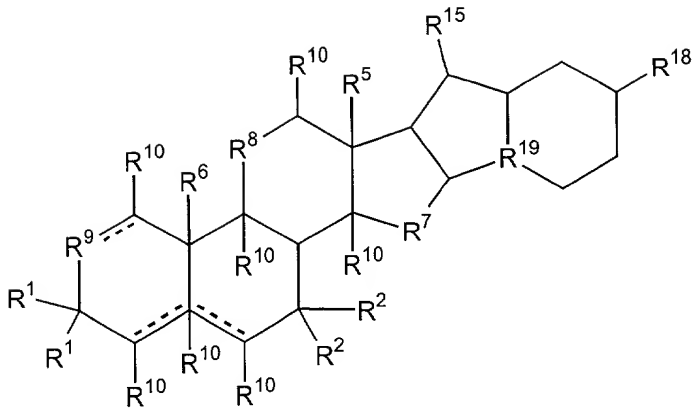
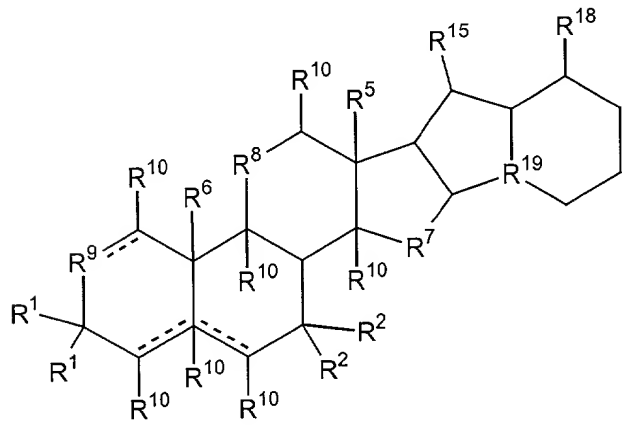


or



;

wherein

R^{15}, R^{17} and R^{18} independently are -H, -OR^{PR}, -SR^{PR}, -$N(R^{PR})_2$, -O-Si-$(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, -NO_2, -OSO_3H, -OPO_3H, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted heterocycle, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide, a polymer, or,

one or more of R^{15}, R^{17} and R^{18} independently are =O, =S, =N-OH, =CH_2 or a spiro ring and the hydrogen atom that is bonded to the same carbon atom is absent;

R^{16} independently are -CH_2-, -O-, -S- or -NH-; and

R^{19} is nitrogen or CH.

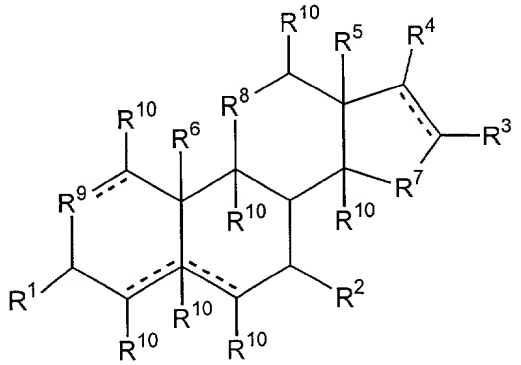
7. The composition of claim 6 wherein one, two or three of R^7, R^8 and R^9 are independently -O-, -S-, or -NH- or wherein one or both of R^5 and R^6 independently are -H, $-CH_3$, $-CH_2OR^{PR}$, $-CH_2SR^{PR}$, $-CH_2O-C(O)-C_{1-10}$ alkyl, $-CH_2S-C(O)-C_{1-10}$ alkyl, $-CH_2O-C(O)-C_{1-10}$ alkenyl, $-CH_2S-C(O)-C_{1-10}$ alkenyl, $-CH_2O-C(O)-C_{0-4}$ alkyl-heterocycle, $-CH_2S-C(O)-C_{0-4}$ alkyl-heterocycle, $-CH_2O-C(O)-C_{0-4}$ alkyl-phenyl, $-CH_2S-C(O)-C_{0-4}$ alkyl-phenyl, wherein any C_{1-10} alkyl, heterocycle or phenyl moiety is optionally substituted with one or more substituents.

8. The composition of claim 7 wherein the one or more substituents are one, two, three or more independently selected -O-, =O, $-OR^{PR}$, -S-, =S, $-SR^{PR}$, -NH-, $-N(R^{PR})_2$ or -C(O)-NH-, wherein each R^{PR} independently is -H or a protecting group.

9. The composition of claim 5 wherein R^1 and R^4 independently are -OH, -O-alkyl, -O-C(O)-alkyl, =O, -SH, -S-alkyl, -S-C(O)-alkyl or =S, and R^2 and R^3 is -H, -OH, -O-alkyl, -O-C(O)-alkyl, =O, -SH, -S-alkyl, -S-C(O)-alkyl or =S.

10. The composition of claim 5 wherein the formula 1 compound is a compound named in compound groups 1 through 54-53-52-51a6-50c27-49c27-48-47-46-45-44-43-42-41-40-39-38-37-36-35-34-33-32-31-30-29-28-27-39-38-37-36-35-34-33-32-31-30-29-28-27-26-25-23-21-17-10-8-6.

11. A compound of formula 1



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wherein,

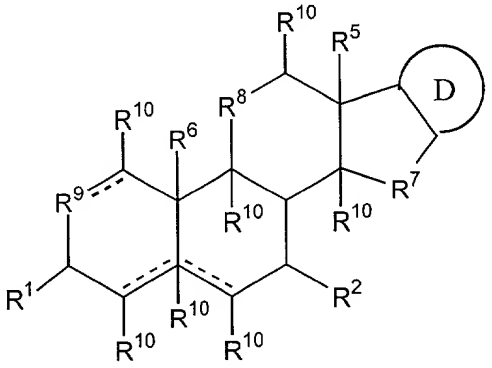
R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} independently are -H, $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-O-Si-(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, $-NO_2$, $-OSO_3H$, $-OPO_3H$, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a

thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted heterocycle, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide, a polymer, or,

one, two or more of R^1, R^2, R^3, R^4, R^5, R^6 and R^{10} independently are =O, =S, =N-OH, $=CH_2$ or a spiro ring and the hydrogen atom that is bonded to the same carbon atom is absent, or,

one or more of two adjacent R^1-R^6 and R^{10} comprise an independently selected ketal or thioketal, or

R^3 and R^4 together comprise a structure of formula 2



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R^7 is $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-C(R^{10})_2-$, $-C(R^{10})_2-O-C(R^{10})_2-$, $-C(R^{10})_2-S-C(R^{10})_2-$, $-C(R^{10})_2-NR^{PR}-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$;

R^8 and R^9 independently are $-C(R^{10})_2-$, $-C(R^{10})_2-C(R^{10})_2-$, -O-, $-O-C(R^{10})_2-$, -S-, $-S-C(R^{10})_2-$, $-NR^{PR}-$ or $-NR^{PR}-C(R^{10})_2-$, or one or both of R^8 or R^9 independently are absent, leaving a 5-membered ring;

R^{13} independently is C_{1-6} alkyl;

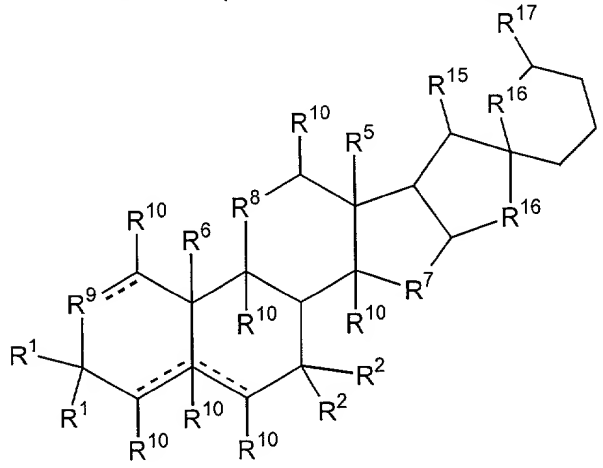
D is a heterocycle or a 4-, 5-, 6- or 7-membered ring that comprises saturated carbon atoms, wherein 1, 2 or 3 ring carbon atoms of the 4-, 5-, 6- or 7-membered ring are optionally independently substituted with -O-, -S- or $-NR^{PR}-$ or where 1, 2 or 3 hydrogen atoms of the heterocycle or where 1 or 2 hydrogen atoms of the 4-, 5-, 6- or 7-membered ring are substituted with $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, $-O-Si-(R^{13})_3$, -CHO, -

CHS, -CH=NH, -CN, -NO_2, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide or a polymer, or,

one or more of the ring carbons are substituted with =O, =S, =N-OH, $=CH_2$ or a spiro ring, or

D comprises two 5- or 6-membered rings, wherein the rings are fused or are linked by 1 or 2 bonds, wherein two or three of R^7, R^8 and R^9 are not $-CHR^{10}-$ or $-C(R^{10})_2-$.

12. The compound of claim 11 wherein formula 2 has the structure



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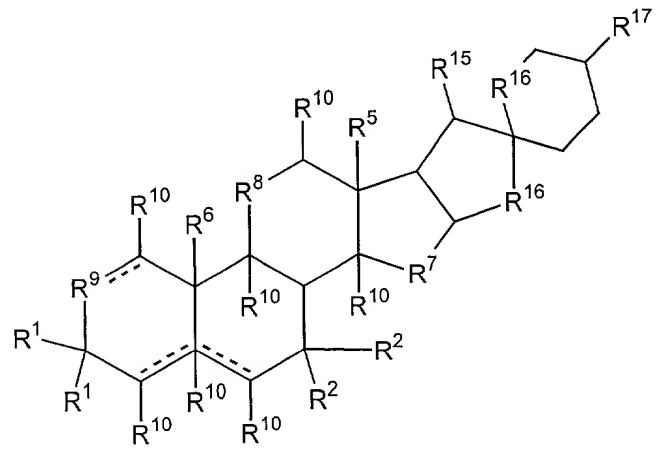

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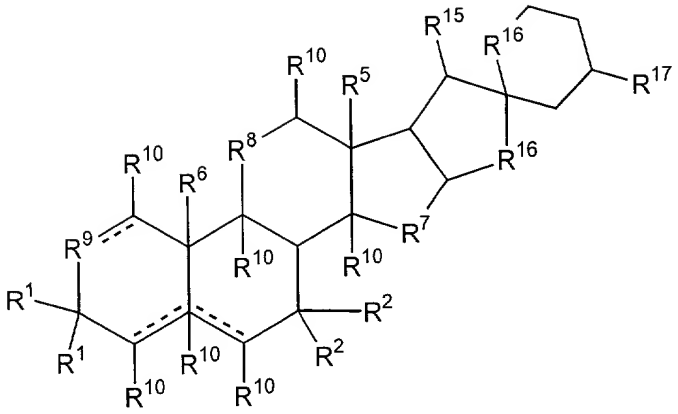

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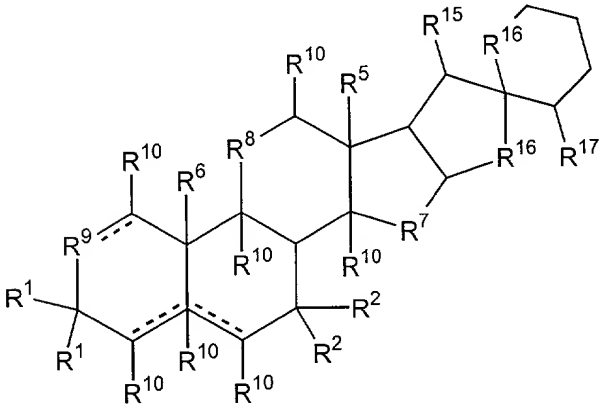

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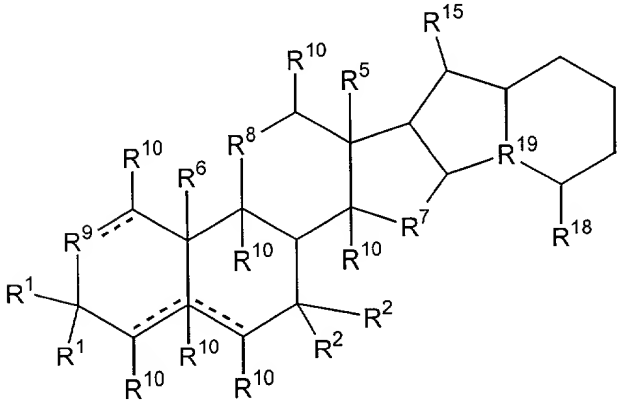

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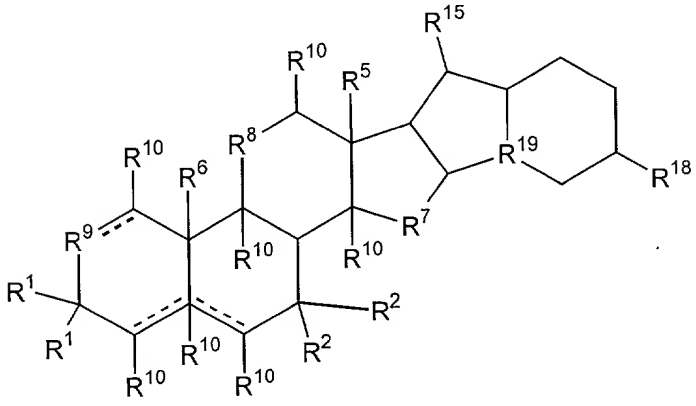

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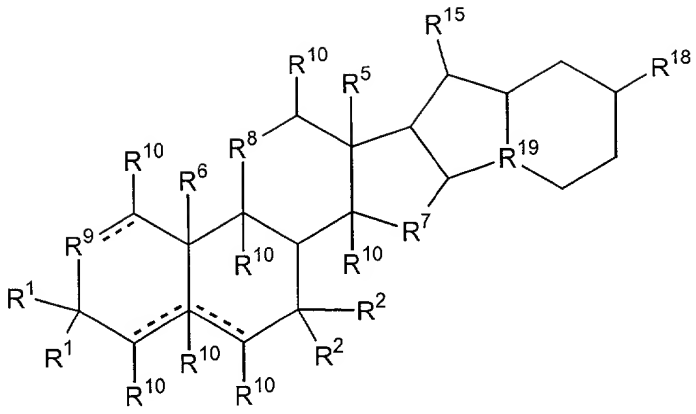
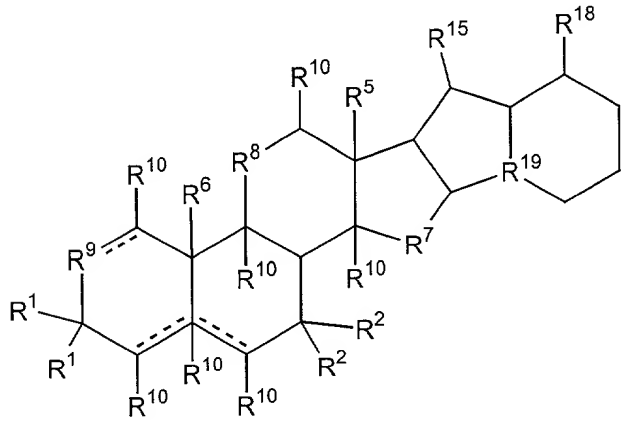


or



;

wherein

R^{15}, R^{17} and R^{18} independently are -H, -OR^{PR}, -SR^{PR}, -$N(R^{PR})_2$, -O-Si-$(R^{13})_3$, -CHO, -CHS, -CH=NH, -CN, -SCN, -NO_2, -OSO_3H, -OPO_3H, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide, a polymer, or,

one or more of R^{15}, R^{17} and R^{18} independently are =O, =S, =N-OH, $=CH_2$ or a spiro ring and the hydrogen atom that is bonded to the same carbon atom is absent;

R^{16} independently are $-CH_2-$, -O-, -S- or -NH-; and

R^{19} is nitrogen or CH.

13. The compound of claim 12 wherein no double donds are present, or wherein one double bond is present.

14. The compound of claim 12 wherein one, two or three of R^7, R^8 and R^9 are independently -O-, -S-, or -NH- or wherein one or both of R^5 and R^6 independently are -H, $-CH_3$, $-CH_2OR^{PR}$, $-CH_2SR^{PR}$, -CHO, -CHS, -CH=NH, $-CH_2O-C(O)-C_{1-10}$ alkyl, $-CH_2S-C(O)-C_{1-10}$ alkyl, $-CH_2O-C(O)-C_{1-10}$ alkenyl, $-CH_2S-C(O)-C_{1-10}$ alkenyl, $-CH_2O-C(O)-C_{0-4}$ alkyl-heterocycle, $-CH_2S-C(O)-C_{0-4}$ alkyl-heterocycle, $-CH_2O-C(O)-C_{0-4}$ alkyl-phenyl, $-CH_2S-C(O)-C_{0-4}$ alkyl-phenyl, wherein any C_{1-10} alkyl, C_{1-10} alkenyl, heterocycle or phenyl moiety is optionally substituted with one or more independently selected substituents.

15. The compound of claim 14 wherein the one or more independently selected substituents are one, two, three or more independently selected -O-, =O, $-OR^{PR}$, -S-, =S, $-SR^{PR}$, -NH-, $-N(R^{PR})_2$ or -C(O)-NH-, wherein each R^{PR} independently is -H or a protecting group.

16. The compound of claim 15 wherein R^1 and R^4 independently are -OH, -O-alkyl, -O-C(O)-alkyl, =O, -SH, -S-alkyl, -S-C(O)-alkyl or =S, and R^2 and R^3 independently are -H, -OH, -O-alkyl, -O-C(O)-alkyl, =O, -SH, -S-alkyl, -S-, -C(O)-alkyl or =S.

17. The compound of claim 11 wherein the formula 1 compound is a compound named in compound groups 1 through 54-53-52-51a6-50c27-49c27-48-47-46-45-44-43-42-41-40-39-38-37-36-35-34-33-32-31-30-29-28-27-39-38-37-36-35-34-33-32-31-30-29-28-27-26-25-23-21-17-10-8-6.

18. The compound of claim 17 wherein one or two of R^7, R^8 and R^9 independently is -O-, -S- or -NH-.

19. The compound of claim 17 wherein one or two of R^7, R^8 and R^9 independently is -O-, -S- or -NH- and R^1, R^2 and R^4 independently are -OH, -SH or group that can hydrolyze to -OH or -SH.

20. The compound of claim 19 wherein R^1 is in the α-configuration and R^5 and R^6 are both in the α-configuration and R^5 and R^6 independently are $-CH_3$ or $-CH_2OH$ or a group that can hydrolyze to $-CH_2OH$.

21. The compound of claim 20 wherein R^2 is in the α-configuration and any hydrogen at the 5-position is in the α-configuration.

22. The compound of claim 21 wherein the formula 1 compound is an analog of 16α-bromo-3β-hydroxy-5α-androstan-17-one, 16α-bromo-3β,7β-dihydroxy-5α-androstan-17-one, 16α-bromo-3β,7β,17β-trihydroxy-5α-androstane, 16α-bromo-3β,7α-dihydroxy-5α-androstan-17-one, 16α-bromo-3β,7α,17β-trihydroxy-5α-androstane, 16α-bromo-3α,7β-dihydroxy-5α-androstan-17-one, 16α-bromo-3β,7β,17α-trihydroxy-5α-androstane, 16α-bromo-3α,7α-dihydroxy-5α-androstan-17-one, 16α-bromo-3β,7α,17α-trihydroxy-5α-androstane, 16α-bromo-3β-hydroxy-5α-androstan-7,17-dione, 16α-bromo-3α-hydroxy-5α-androstan-7,17-dione, 16α-bromo-7β-hydroxy-5α-androstan-3,17-dione, 16α-bromo-7α-hydroxy-5α-androstan-3,17-dione, 3β-hydroxy-5α-androstan-17-one, 3β,7β-dihydroxy-5α-androstan-17-one, 3β,7β,17β-trihydroxy-5α-androstane, 3β,7α-dihydroxy-5α-androstan-17-one, 3β,7α,17β-trihydroxy-5α-androstane, 3α,7β-dihydroxy-5α-androstan-17-one, 3β,7β,17α-trihydroxy-5α-androstane, 3α,7α-dihydroxy-5α-androstan-17-one, 3β,7α,17α-trihydroxy-5α-androstane, 3β-hydroxy-5α-androstan-7,17-dione, 3α-hydroxy-5α-androstan-7,17-dione, 7β-hydroxy-5α-androstan-3,17-dione, 7α-hydroxy-5α-androstan-3,17-dione, 16α-bromo-3β-hydroxy-5-androstene-17-one, 16α-bromo-3β,7β-dihydroxy-5-androstene-17-one, 16α-bromo-3β,7β,17β-trihydroxy-5-androstene, 16α-bromo-3β,7α-dihydroxy-5-androstene-17-one, 16α-bromo-3β,7α,17β-trihydroxy-5-androstenee, 16α-bromo-3α,7β-dihydroxy-5-androstene-17-one, 16α-bromo-3β,7β,17α-trihydroxy-5-androstenee, 16α-bromo-3α,7α-dihydroxy-5-androstene-17-one, 16α-bromo-3β,7α,17α-trihydroxy-5-androstenee, 16α-bromo-3β-hydroxy-5-androstene-7,17-dione, 16α-bromo-3α-hydroxy-5-androstene-7,17-dione, 16α-bromo-7β-hydroxy-5-androstene-3,17-dione, 16α-bromo-7α-hydroxy-5-androstene-3,17-dione, 3β-hydroxy-5-androstene-17-one, 3β,7β-dihydroxy-5-

androstene-17-one, 3β,7β,17β-trihydroxy-5-androstene, 3β,7α-dihydroxy-5-androstene-17-one, 3β,7α,17β-trihydroxy-5-androstene, 3α,7β-dihydroxy-5-androstene-17-one, 3β,7β,17α-trihydroxy-5-androstene, 3α,7α-dihydroxy-5-androstene-17-one, 3β,7α,17α-trihydroxy-5-androstene, 3β-hydroxy-5-androstene-7,17-dione, 3α-hydroxy-5-androstene-7,17-dione, 7β-hydroxy-5-androstene-3,17-dione, 7α-hydroxy-5-androstene-3,17-dione, 16α-bromo-3β-hydroxy-4-androstene-17-one, 16α-bromo-3β,7β-dihydroxy-4-androstene-17-one, 16α-bromo-3β,7β,17β-trihydroxy-4-androstene, 16α-bromo-3β,7α-dihydroxy-4-androstene-17-one, 16α-bromo-3β,7α,17β-trihydroxy-4-androstenee, 16α-bromo-3α,7β-dihydroxy-4-androstene-17-one, 16α-bromo-3β,7β,17α-trihydroxy-4-androstenee, 16α-bromo-3α,7α-dihydroxy-4-androstene-17-one, 16α-bromo-3β,7α,17α-trihydroxy-4-androstenee, 16α-bromo-3β-hydroxy-4-androstene-7,17-dione, 16α-bromo-3α-hydroxy-4-androstene-7,17-dione, 16α-bromo-7β-hydroxy-4-androstene-3,17-dione, 16α-bromo-7α-hydroxy-4-androstene-3,17-dione, 3β-hydroxy-4-androstene-17-one, 3β,7β-dihydroxy-4-androstene-17-one, 3β,7β,17β-trihydroxy-4-androstene, 3β,7α-dihydroxy-4-androstene-17-one, 3β,7α,17β-trihydroxy-4-androstene, 3α,7β-dihydroxy-4-androstene-17-one, 3β,7β,17α-trihydroxy-4-androstene, 3α,7α-dihydroxy-4-androstene-17-one, 3β,7α,17α-trihydroxy-4-androstene, 3β-hydroxy-4-androstene-7,17-dione, 3α-hydroxy-4-androstene-7,17-dione, 7β-hydroxy-4-androstene-3,17-dione, 7α-hydroxy-4-androstene-3,17-dione, 16α-bromo-3β-hydroxy-1-androstene-17-one, 16α-bromo-3β,7β-dihydroxy-1-androstene-17-one, 16α-bromo-3β,7β,17β-trihydroxy-1-androstene, 16α-bromo-3β,7α-dihydroxy-1-androstene-17-one, 16α-bromo-3β,7α,17β-trihydroxy-1-androstenee, 16α-bromo-3α,7β-dihydroxy-1-androstene-17-one, 16α-bromo-3β,7β,17α-trihydroxy-1-androstenee, 16α-bromo-3α,7α-dihydroxy-1-androstene-17-one, 16α-bromo-3β,7α,17α-trihydroxy-1-androstenee, 16α-bromo-3β-hydroxy-1-androstene-7,17-dione, 16α-bromo-3α-hydroxy-1-androstene-7,17-dione, 16α-bromo-7β-hydroxy-1-androstene-3,17-dione, 16α-bromo-7α-hydroxy-1-androstene-3,17-dione, 3β-hydroxy-1-androstene-17-one, 3β,7β-dihydroxy-1-androstene-17-one, 3β,7β,17β-trihydroxy-1-androstene, 3β,7α-

dihydroxy-1-androstene-17-one, 3β,7α,17β-trihydroxy-1-androstene, 3α,7β-dihydroxy-1-androstene-17-one, 3β,7β,17α-trihydroxy-1-androstene, 3α,7α-dihydroxy-1-androstene-17-one, 3β,7α,17α-trihydroxy-1-androstene, 3β-hydroxy-1-androstene-7,17-dione, 3α-hydroxy-1-androstene-7,17-dione, 7β-hydroxy-1-androstene-3,17-dione or 7α-hydroxy-1-androstene-3,17-dione, wherein one, two or three independently selected moieties hydrolyzable to a hydroxyl group are optionally bonded to one, two or three hydroxyl or thiol groups, and wherein one or two of R^7, R^8 and R^9 are not $-C(R^{10})_2-$.

23. A composition comprising a compound of claim 22, and one or more excipients.

24. The composition of claim 23 wherein the one or excipients is a solid excipient, a nonaqueous liquid excipient or water.

25. The composition of claim 24, wherein the composition is a unit dosage formulation that comprises about 5 to about 1000 mg of one formula 1 compound.

26. A product produced by the process of contacting the compound of claim 11, and one or more excipients suitable for human pharmaceutical use or for veterinary use.

27. The product of claim 26 wherein the excipient is a solid excipient, a nonaqueous liquid excipient or water.

28. The product of claim 27, wherein the product is a unit dosage formulation that comprises about 3.5 mg to about 1000 mg of one formula 1 compound.

29. A method comprising administering to a subject or delivering to the subject's tissues an effective amount of a composition of claim 11 wherein the subject has or is susceptible to a pathogen infection or a malignancy, whereby the pathogen infection or the malignancy is prevented or delayed or whereby one or more symptoms of the pathogen infection or the malignancy is ameliorated or whereby the replication of a pathogen primarily responsible for the pathogen infection is inhibited or whereby replication of the malignant cells is inhibited, or whereby at least a portion of an extracellular pathogen primarily responsible for the pathogen infection, or cells infected by the pathogen or the malignant cells are killed, or

whereby the malignant cell population is reduced, or whereby the degree of pathogen replication is reduced.

30. The method of claim 29 further comprising intermittently administering to the subject or delivering to the subject's tissues an effective amount of the composition of claim 11.

31. The method of claim 30 wherein (a) the composition of claim 11 is administered to the subject or delivered to the subject's tissues (i) one, two or three times per day for 1, 2, 3, 4 or 5 consecutive days or (ii) one, two or three times per day every other day over a period of 3, 5, 7 or 9 days; (b) not administering the composition of claim 15 for at least about 28 days to at least about 8 months from the last day of dosing in step (a); (c) administering to the subject or delivering to the subject's tissues the composition of claim 15 (i) one, two or three times per day for 1, 2, 3, 4 or 5 consecutive days or (ii) one, two or three times per day every other day over a period of 3, 5, 7 or 9 days; and (d) optionally repeating steps (a), (b) and (c) 1, 2, 3, 4, 5 or more times.

32. The method of claim 30 wherein (a) the composition of claim 15 is administered to the subject or delivered to the subject's tissues once per day every other day over a period of 5 days; (b) not administering the composition of claim 15 for 2 days; (c) and then repeating step (a); and (d) optionally repeating steps (a), (b) and (c) 1, 2, 3 or more times.

33. The method of claim 32 wherein about 0.05 mg/kg to about 25 mg/kg of the formula 1 compound that is present in the composition of claim 15 is administered to the subject or delivered to the subject's tissues.

34. The method of claim 1 wherein the modulation is an enhanced Th1 immune response or a reduced Th2 immune response.

35. The method of claim 34 wherein the the subject has an immunosuppression condition (a suboptimal Th1 immune response) or an unwanted immune response (excess Th2 immune response), either or both of which are associated with (1) a pathogen infection selected from a viral infection, an intracellular bacterial infection, an extracellular bacterial infection, a fungal infection, a yeast infection, an extracellular parasite infection, an intracellular parasite infection, a

protozoan parasite infection and a multicellular parasite infection, (2) an autoimmune disease, (3) a malignancy or a precancer, (4) a chemotherapy, a radiation therapy, an immunosuppressive therapy, an anti-infective agent therapy, a wound, a burn, the presence of an immunosuppressive molecule, or gastrointestinal irritation or an inflammation condition optionally selected from or associated with irritable bowel disease, Crohn's disease or chronic diarrhea or (5) any combination of the foregoing.

36. The method of claim 35 wherein the subject's immunosuppression condition is ameliorated or the unwanted immune response is reduced.

37. The method of claim 36 wherein the subject's innate immunity, specific immunity or both is enhanced.

38. The method of claim 35 wherein the subject's viral infection, intracellular bacterial infection, extracellular bacterial infection, fungal infection, yeast infection, extracellular parasite infection, intracellular parasite infection, protozoan parasite, multicellular parasite, autoimmune disease, cancer, precancer, chemotherapy, radiation therapy, immunosuppressive therapy, anti-infective agent therapy, a wound, a burn, or the presence of an immunosuppressive molecule, gastrointestinal irritation or an inflammation condition optionally selected from or associated with irritable bowel disease, Crohn's disease or chronic diarrhea, or any combination of the foregoing is selected from (a) a DNA virus infection or an RNA virus infection; (b) a mycoplasma infection, a *Listeria* infection or a *Mycobacterium* infection; (c) a *Streptococcus* infection, a *Staphylococcus* infection, a *Vibrio* infection, a *Salmonella* infection, a *Shigella* infection, an enterotoxigenic, enteropathogenic, enteroinvasive or enterohemorrhagic *E. coli* infection, a *Yersinia* infection, a *Campylobacter* infection, a *Pseudomonas* infection, a *Borrelia* infection, a *Legionella* infection and a *Haemophilus* infection; (d) pulmonary *Aspergillosis*, mucosal or oropharyngealcandidiasis and juvenile paracoccidiomycosis; (e) a *Candida* infection and a *Cryptococcus* infection; (f) systemic lupus erythematosis, arthritis and diabetes; (g) a solid or a disseminated cancer selected from ovarian cancer, cervical cancer, breast cancer, prostate cancer, liver cancer or carcinoma, a glioma, a lymphoma, a leukemia and a colon cancer; (h) benign prostatic hyperplasia and recurrent condylomata acuminata; (i) adriamycin treatment, cisplatin treatment, mitomycin C

treatment, amphotericin B treatment; (j) a γ-radiation therapy; (k) nucleoside analog treatment for viral infection or or cancer; (l) surgical wounds and accidental wounds; (m) cyclosporin treatment and corticosteroid treatment; (n) an inflammation condition optionally selected from or associated with asthma, irritable bowel disease, Crohn's disease, chronic diarrhea; or (o) any combination of (a) through (n).

39. The method of claim 38 wherein the subject is a mammal.

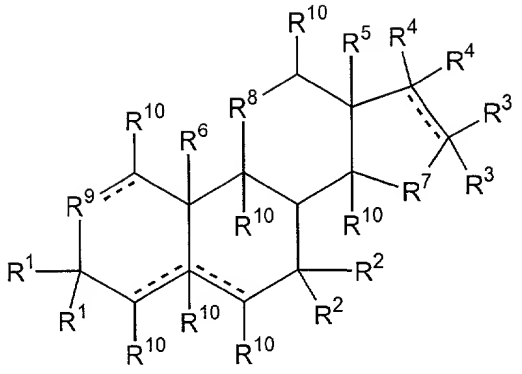
40. The method of claim 38 wherein the DNA virus infection or the RNA virus infection is selected from a HSV, CMV, HBV, HCV, HIV, SHIV, SIV, FIV, EBV, HSV-1, HSV-2, HSV-6, HHV-6, HHV-8, adeno-associated virus, measles virus, poxvirus, Poliovirus, human rhinovirus, human papilloma virus and animal papilloma virus infection.

41. The method of claim 40 wherein the subject is a human having an HIV-1 or HIV-2 infection, wherein the subject's CD4 cell count is about 25 to about 100 $CD4^+$ cells/mm^3.

42. The method of claim 41 wherein the subject is suffering from one or more complications or co-infections associated with AIDS.

43. The method of claim 40 wherein the subject has a pathogen infection or a malignancy and the pathogen or the malignancy does not become resistant to the formula 1 compound over a time normally associated with the development of measurable resistance to any traditional pathogen or malignancy chemotherapy or radiation therapy in at least about 30% of the subjects who are treated with a chemotherapy or a radiation therapy for the pathogen infection or the malignancy other than a formula 1 compound.

44. A method to prevent or treat an immune disregulation or deficiency condition in a subject in need thereof comprising administering to the subject, or delivering to the subject's tissues, an effective amount of a compound of formula 1



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wherein, R^1-R^{10} have the definitions given in claim 1 and 1, 2 or 3 of R^7, R^8 and R^9 are not $-CH_2-$, or one of R^1-R^6 and R^{10} is an amino acid.

45. The method of claim 44 wherein R^7 is -O-, -NH- or -S-.

46. The method of claim 44 wherein R^8 is -O-, -NH- or -S-.

47. The method of claim 44 wherein R^9 is -O-, -NH-, =N- or -S-.

48. The method of claim 44 wherein two of R^7, R^8 and R^9 are not $-CH_2-$.

49. The method of claim 48 wherein R^7 is -O- and R^8 is -O-, R^7 is -O- and R^9 is -O-, R^8 is -O- and R^9 is -O-, R^7 is -O- and R^8 is -N-, R^7 is -O- and R^9 is -NH- or =N-, R^8 is -O- and R^9 is -NH- or =N-, R^7 is -O- and R^8 is -S-, R^7 is -O- and R^9 is -S-, R^8 is -O- and R^9 is -S-, R^7 is -NH- and R^8 is -NH-, R^7 is -NH- and R^9 is -NH- or =N-, R^8 is -NH- and R^9 is -NH- or =N-, R^7 is -NH- and R^8 is -O-, R^7 is -NH- and R^9 is -O-, R^8 is -NH- and R^9 is -O-, R^7 is -NH- and R^8 is -S-, R^7 is -NH- and R^9 is -S-, R^8 is -NH- and R^9 is -S-, R^7 is -S- and R^8 is -S-, R^7 is -S- and R^9 is -S-, R^8 is -S- and R^9 is -S-, R^7 is -S- and R^8 is -N-, R^7 is -S- and R^9 is -NH- or =N-, R^8 is -S- and R^9 is -NH- or =N-, R^7 is -S- and R^8 is -O-, R^7 is -S- and R^9 is -O-, or R^8 is -S- and R^9 is -O-.

50. The method of claim 44 wherein none of R^7, R^8 and R^9 are $-CH_2-$.

51. The method of claim 44 wherein the immune disregulation or deficiency condition is associated with an infection, a cancer or a precancer, or the immune disregulation or deficiency condition is an inflammation condition, an autoimmune disease or a neurodegenerative disorder.

52. The method of claim 1 wherein the subject has a pathogen infection, a cancer or a precancer and subject's antibody response to one or more of the pathogen's antigens or one or more of the cancr's or precancer's antigens is enhanced.

53. 16α-Bromo-3β-hydroxy-5α-androstan-17-one hemihydrate substantially free of other forms of 16α-bromo-3β-hydroxy-5α-androstan-17-one.

54. The 16α-bromo-3β-hydroxy-5α-androstan-17-one hemihydrate substantially free of other forms of 16α-bromo-3β-hydroxy-5α-androstan-17-one of claim 53 wherein 16α-bromo-3β-hydroxy-5α-androstan-17-one hemihydrate comprises at least about 55% w/w of the 16α-bromo-3β-hydroxy-5α-androstan-17-one that is present.